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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
REIDEL, JESSICA L	
ART UNIT	**PAPER NUMBER**
3766	

DATE MAILED: 10/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/803,570	BURNES ET AL.	
	Examiner	Art Unit	
	Jessica L. Reidel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,14,19-29,32 and 37-50* is/are rejected.

7)☐ Claim(s) *12,13,15-18,30,31,33-36 and 51* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 March 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the drawings appear to be informal. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

2. Figures 1-2 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The disclosure is objected to because of the following informalities: *Cross Reference to Related Applications* section must be updated with the appropriate application serial numbers (Pilmeyer and van Gelder and B. Rerek-Petric) and issued patent number (Hill). Appropriate correction is required.

4. The abstract of the disclosure is objected to because the language "the present invention" (line 1) and "the invention" (lines 2-3) should not be used. The Examiner suggests substituting

the words "The biventricular pacemaker". Appropriate correction is required. See MPEP § 608.01(b).

Claim Objections

5. Claim 20 is objected to because of the following informalities: the claim recites the limitation "A method" (line 1) but depends from an apparatus claim. The Examiner suggest changing the claim to recite the limitation "An apparatus". Appropriate correction is required.

6. Claims 50-51 are objected to because of the following informalities: the claims recite the limitation "the fusion based cardiac pacing regimen" and depend from Claim 1 which does not recite such limitation. Appropriate correction is required.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. As written Claims 5, 23 and 41 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, the claims recite parts of the human body per se without referring to any related apparatus features or method steps. To overcome this rejection, the Examiner recommends changing the language of Claim 5 to read as follows:

> "5. A method of claim 4, wherein the step of delivering a pre-excitation pulse to said at least one electrode in the left ventricular chamber comprises delivering the pulse to a portion of one of:
> a coronary sinus,
> a portion of a great vein,
> a portion of a vessel branching from the great vein."

The language of Claims 23 and 41 should be modified similarly to overcome4 the 35 U.S.C 101 rejections against them.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1-4, 6-7, 10-11, 14, 19-22, 24-25, 28-29, 32, 37-40, 42-43, 46-47 and 50 are rejected under 35 U.S.C. 102(e) as being anticipated by Ding et al. (U.s. 2005/0137630) (herein Ding). As to Claims 1, 3-4, 10-11, 19, 21-22, 28-29, 37, 39-40 and 46-47, Ding discloses an apparatus and computer-readable medium 10, 12 (see Ding Fig. 1) that carry out a method of bi-ventricular, fusion-pacing therapy delivery to a non-synchronous pair of ventricles, including delivery of a single ventricular pre-excitation pacing pulse to a relatively late activated ventricular chamber to promote mechanical synchrony between the late activated ventricular chamber and a relatively more rapid, intrinsically conducting ventricular chamber (see Ding page 3, paragraphs 16-18) comprising measuring an intrinsic atrio-ventricular AV delay interval for a first-to-depolarize ventricular chamber (V1, right ventricle) for at least one prior cardiac cycle and delivering during a subsequent cardiac cycle at least one ventricular pre-excitation pacing pulse to a second-to-depolarize ventricular chamber (V2, left ventricle). Ding also discloses that the ventricular pre-excitation pacing pulse is delivered at the expiration of an AV delay interval AVD, read as a V2 pacing interval, wherein the V2 pacing interval is temporally shorter than the

measured intrinsic atrio-ventricular AV delay interval of the right ventricular chamber (see Ding Fig. 3 and page 6, paragraph 40).

11. As to Claims 2, 20 and 38, Ding discloses that the techniques for setting resynchronization pacing parameters as described may be implemented in a number of embodiments such as where the step of measuring the atrio-ventricular AV delay interval further comprises calculating an average AV delay interval or using a lookup table and procedure (see Ding page 4, paragraph 27).

12. As to Claims 6-7, 24-25 and 42-43, Ding discloses a left atrial sensing/pacing ring electrode 53a and tip electrode 53b of bipolar lead 53c, and a right atrial sensing/pacing ring electrode 43a and tip electrode 43b of bipolar lead 43c. Ding also discloses a right ventricular sensing/pacing ring electrode 23a and tip electrode 23b of bipolar lead 23c and a left ventricular sensing/pacing ring electrode 33a and tip electrode 33b of bipolar lead 33c. Ding further discloses that in this embodiment, the device is equipped with bipolar leads that include two electrodes, which are used for outputting a pacing pulse and/or sensing intrinsic activity. (see Ding page 2, paragraph 13).

13. As to Claims 14, 32 and 50, Ding discloses that in order to optimally specify the bi-ventricular pacing parameters for a particular patient, clinical hemodynamic testing may be performed after implantation where the parameters are varied as cardiac function is assessed. In order to accomplish this, Ding further discloses that a patient may be given resynchronization stimulation while varying pre-excitation timing parameters in order to determine the values of the parameters that result in maximum cardiac performance, as determined by measuring a parameter reflective of cardiac function such as maximum left ventricular pressure change

(dP/dt), arterial pulse pressure, or measurements of cardiac output (see Ding page 3, paragraph 21).

14. Claims 1-11, 14, 19-29, 32, 37-47 and 50 are rejected under 35 U.S.C. 102(e) as being anticipated by Hill (U.S. 6,871,096).

The applied reference has a common Assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

15. As to Claims 1-4, 10-11, 19-22, 28-29, 37-40 and 46-47, Hill discloses an apparatus and computer-readable medium that carry out a method of bi-ventricular, fusion-pacing therapy delivery to a non-synchronous pair of ventricles, including delivery of a single ventricular pacing pulse to a relatively late activated ventricular chamber to promote mechanical synchrony between the late activated ventricular chamber and a relatively more rapid, intrinsically conducting ventricular chamber comprising measuring an intrinsic atrio-ventricular AV delay interval for a first-to-depolarize ventricular chamber (V1, right ventricle) for at least one prior cardiac cycle and delivering during a subsequent cardiac cycle at least one ventricular pacing pulse to a second-to-depolarize ventricular chamber (V2, left ventricle). Hill also discloses that the ventricular pre-excitation pacing pulse is delivered at the expiration of a V2 pacing interval, wherein the V2 pacing interval is temporally shorter than the intrinsic atrio-ventricular AV delay interval of the V1 chamber (see Hill column 16, lines 43-67, column 17, lines 1-5 and column

19, lines 24-54). Hill further discloses that the ventricular pacing pulses are pre-excitation pacing pulses (see Hill column 7, lines 1-15).

16. As to Claims 5, 23 and 41, Hill discloses that the bipolar, endocardial coronary sinus lead 52 is passed through a vein and the RA chamber of the heart 10, into the coronary sinus and then inferiorly in a branching vessel to extend the proximal and distal LV CS pace/sense tip electrodes 48 and 50 alongside the LV chamber. The distal end of such a CS lead is advanced through the superior vena cava, the right atrium, the ostium of the coronary sinus, the coronary sinus, and into a coronary vein descending from the coronary sinus, such as the lateral or posteriolateral vein (see Hill column 10, lines 1-10). Hill also discloses an alternative embodiment the LV CS pace/sense tip electrodes 28 and 30 may reside in a portion of a great vein or a portion of a vessel branching from the great vein (see Hill column 10, lines 18-25).

17. As to Claims 6-9, 24-27 and 42-45, Hill discloses that the ventricular pre-excitation pacing pulse is delivered between a tip 40 and a ring 38 pacing electrodes (see Hill column 9, lines 50-55) and that the measuring step occurs between at least one of a tip and a ring pacing electrode, a pair of electrodes, an epicardial electrode and a second electrode, a subcutaneous electrode and the second electrode (see Hill column 9, lines 30-67). Hill further discloses that control circuit 350 selects associated sense electrode pairs to be coupled with the sense amplifies of the system (see Hill column 13, lines 31-50). It is inherent that at least one of the electrodes of the LV CS lead 52 is adapted to couple to an anterior portion of the left ventricle or epicardially to the left ventricle due to Hill, column 10, lines 6-25.

18. As to Claims 14, 32 and 50, Hill discloses an IPG circuit 300, programmed in a rate responsive mode, wherein signals output by one or more physiologic sensors are employed as a

rate control parameter via patient activity sensor 322. Hill also discloses that the activity sensor 316 monitors a physiologic cardiac parameter such as QT time intervals, oxygen levels, pressure levels, pH levels and respiration levels during delivery of the fusion-based cardiac pacing regimen (see Hill column 10, lines 66-67 and column 11, lines 1-21).

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

20. Claims 5, 9, 23, 27, 41 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding in view of Mower (U.S2005/0055058). As to Claims 5, 23 and 41, Ding discloses the claimed invention except that the at least one electrode adapted to be coupled to a left ventricular chamber is not adapted to be positioned via one of a coronary sinus, a portion of a great vein, or a portion of a vessel branching from the great vein.

Mower, however, discloses a method and apparatus for intrachamber resynchronization that senses cardiac conduction and determines the progress of contraction of the heart. Based on the progress of contraction, the left ventricular chamber of the heart is then stimulated at a plurality of locations for the purpose of improving hemodynamic performance and increasing cardiac output in a patient who is suffering from congestive heart failure. Mower also discloses that in an alternative embodiment a pre-excitation voltage may be applied to pre-condition a portion of the heart for the resynchronization therapy (see Mower Abstract, page 1, paragraphs 12-14 and page 2, paragraph 15). Mower further discloses that the left ventricular pacing

electrode 404 is safely advanced through the superior vena cava, the right atrium, the ostium of the coronary sinus (CS), the CS, and into a coronary vein descending from the CS, and is implanted at a desired pacing site in the coronary vein (see Mower page 5, paragraphs 60-61). Therefore it would have been obvious to one having ordinary skill in the art that the time the invention was made to modify Ding in view of Mower to include an electrode adapted to be coupled to a left ventricular chamber via the coronary sinus in order to provide a safe system for increased hemodynamic efficiency of a heart experiencing a conduction deficiency and to ensure a more coordinated and simultaneous ventricular depolarization of both left and right ventricles of the heart.

21. As to Claims 9, 27 and 45, Ding discloses the claimed invention except that the at least one electrode for delivering pre-excitation pulses is not adapted to couple epicardially to the left ventricular chamber.

Mower, however, discloses a method and apparatus for intrachamber resynchronization that senses cardiac conduction and determines the progress of contraction of the heart. Based on the progress of contraction, the left ventricular chamber of the heart is then stimulated at a plurality of locations for the purpose of improving hemodynamic performance and increasing cardiac output in a patient who is suffering from congestive heart failure. Mower also discloses that in an alternative embodiment a pre-excitation voltage may be applied to pre-condition a portion of the heart for the resynchronization therapy (see Mower Abstract, page 1, paragraphs 12-14 and page 2, paragraph 15). The ventricular electrodes used for pacing the left ventricle can alternatively be placed in other locations besides the coronary sinus or the coronary vein, such as in the epicardial wall of the left ventricle (see Mower page 5, paragraph 62). Therefore it

would have been obvious to one having ordinary skill in the art that the time the invention was made to modify Ding in view of Mower to include an electrode adapted to be coupled the epicardial wall of the left ventricular chamber to provide a safe system for increased hemodynamic efficiency of a heart experiencing a conduction deficiency and to ensure a more coordinated and simultaneous ventricular depolarization of both left and right ventricles of the heart.

22. Claims 6, 8, 24, 26, 42 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding in view of Alt et al. (U.S. 6,370,427) (herein Alt). Ding discloses the claimed invention as discussed above except that the at least one ventricular pre-excitation pacing pulse is not specified to be delivered between a a coil and a can-based electrode, a pair of coil electrodes, an epicardial electrode and a second electrode, or a subcutaneous electrode and the second electrode.

Alt, however, discloses a device and method for dual chamber bi-ventricular pacing and defibrillation comprising a left pacing lead 72 including coil electrode 77, a tip electrode 73 located on a single lead in the anterior portion of the left ventricle (see Alt. Fig. 4) for improved hemodynamic performance in patients with heart failure (see Alt column 3, lines 13-15). Alt further teaches that a can-based electrode may be used which results in a lower excitation to the apex of the left ventricle (see Alt column 3, lines 1-21). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Ding in view of Alt to include an anterior left ventricular electrode configuration comprising a tip and a pair of electrodes or a coil and a can-based electrode to allow the pair of electrodes to be on a single lead to improve the invention's ability to improve hemodynamic performance or to employ a

lower excitatory stimulus to the apex of the left ventricle while simultaneously stimulating the right.

Double Patenting

23. Claims 1-11, 14, 19-29, 32, 37-47 and 50 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22-27 of U.S. Patent No. 6,871,096. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either an obvious broadening of the scope of the patented claims or an obvious variant thereof.

Allowable Subject Matter

24. Claims 12-13, 15-18, 30-31, 33-36 and 51 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

25. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. VanHout (U.S. 2003/0014084) discloses a method and apparatus for monitoring conduction times in a bi-chamber pacing system in a rate-responsive pacemaker. Auricchio et al. (U.S. 5,935,160) discloses a left ventricular access lead for heart failure pacing adapted to be placed in the coronary vein and employed for bi-ventricular pacing.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The examiner can normally be reached on Mon-Thurs 7-4:30 and every other Friday 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 3766

Jessica L. Reidel